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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,433	08/01/2003	Gregory R. Dion	PA1712 (2650/130)	4541

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EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary

Application No.

10/633,433

Applicant(s)

DION, GREGORY R.

Examiner

Theodore J. Stigell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☒ Claim(s) 1-8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/25/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claims 1-8 are objected to because of the following informalities: The preamble of claim 1 does not give a general description of all of the elements in the body. The balloon catheter is only functionally stated in the preamble, but the applicant is claiming the structure of the balloon catheter in the body. This application was examined with consideration given to the limitations of the rotary valve and the balloon catheter. The dependent claims, 2-8, are objected to for the same reason. A suggestion for a new claim is:

A medical device used to occlude a vessel in a body, comprising:
a balloon catheter having a central lumen; including
a rotary valve having a portion of a rotary shaft disposed within a proximal end of the balloon catheter, wherein flow of an inflation fluid through the central lumen of the balloon catheter is controlled by rotating the rotary shaft of the rotary valve.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3763

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5,7-13,15-24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zadno-Azizi et al. (6,050,972).

Zadno-Azizi discloses multiple embodiments of a rotary valve for a balloon catheter that includes all of the limitations of claim 1. See Figures 1-3 and the respective portions of the specification for the first embodiment and Figure 12 and the respective portions of the specification for the second embodiment. The first embodiment shows a hollow guidewire (18) and a rotary shaft (32) of rotary valve (30) disposed within the proximal end of the hollow guidewire (18). The valve (30) can be considered a rotary valve because as it is retracted from the hollow guidewire (18) the biasing spring (37) applies torque to the rotary valve (30) and forces it to rotate. The second embodiment also shows a hollow guidewire (518) and a rotary shaft (568) of rotary valve (550) disposed in the proximal end of hollow guidewire (518).

In regards to claim 2, Zadno-Azizi discloses a rotary valve for a balloon catheter as recited in claim 1 wherein the outer surface of rotary shaft (568) slidably contacts the inner surface of hollow guidewire (518).

In regards to claim 3, Zadno-Azizi discloses a rotary valve for a balloon catheter as recited in claim 1 wherein the rotary shaft (568) includes a channel (572) formed on the distal end.

In regards to claim 4, Zadno-Azizi discloses a rotary valve for a balloon catheter as recited in claim 1 wherein the first portion of the rotary shaft (32) has a slidable

rotating fit within the diameter of hollow guidewire (18) and a second portion (33) that is substantially equal to the diameter of hollow guidewire (18).

In regards to claim 5, Zadno-Azizi discloses a rotary valve for a balloon catheter as recited in claim 1 wherein an inflation hole (22) is formed in a sidewall of the hollow guidewire (18). The second embodiment also has an inflation hole (522) formed in a sidewall of the hollow guidewire (518).

In regards to claim 7, Zadno-Azizi discloses a rotary valve for a balloon catheter as recited in claim 1 wherein a polymeric plug (36) is formed around a portion of the rotary shaft (32).

In regards to claim 8, Zadno-Azizi discloses a rotary valve for a balloon catheter as recited in claim 7 wherein a channel formed by the distal sloping end of plug (86) and the distal end of the shaft (32) allows fluid to flow into the central lumen when the rotary valve is open.

Zadno-Azizi discloses multiple embodiments of a system for treating a vessel in a body that includes all of the limitations of claim 9. See Figures 1-3 and the respective portions of the specification for the first embodiment and Figure 12 and the respective portions of the specification for the second embodiment. The first embodiment shows a hollow guidewire (18), a balloon (20) attached to the distal end of the hollow guidewire (18), and a rotary valve (30) that has a portion of the rotary shaft (32) disposed within the proximal end of the hollow guidewire. The second embodiment includes hollow guidewire (518), a balloon (not shown) attached to the distal end of the catheter (518),

and a rotary valve (550) that includes a rotary shaft (568) disposed within the proximal end of the hollow guidewire.

In regards to claim 10, Zadno-Azizi discloses a system for treating a vessel in a body as recited in claim 9 wherein the outer surface of the rotary shaft (568) slidably contacts a portion of the inner surface of the hollow guidewire (518).

In regards to claim 11, Zadno-Azizi discloses a system for treating a vessel in a body as recited in claim 9 wherein the rotary shaft (568) includes a channel (572) on the distal end.

In regards to claim 12, Zadno-Azizi discloses a system for treating a vessel in a body as recited in claim 9 wherein the first portion of the rotary shaft (32) has a slidable rotating fit within the diameter of hollow guidewire (18) and a second portion (33) that is substantially equal to the diameter of hollow guidewire (18).

In regards to claim 13, Zadno-Azizi discloses a system for treating a vessel in a body as recited in claim 9 wherein an inflation hole (22) is formed in a sidewall of the hollow guidewire (18). The second embodiment also has an inflation hole (522) formed in a sidewall of the hollow guidewire (518).

In regards to claim 15, Zadno-Azizi discloses a system for treating a vessel in a body as recited in claim 9 wherein a polymeric plug (36) is formed around a portion of the rotary shaft (32).

In regards to claim 16, Zadno-Azizi discloses a system for treating a vessel in a body as recited in claim 15 wherein a channel formed by the distal sloping end of plug

Art Unit: 3763

(86) and the distal end of the shaft (32) allows fluid to flow into the central lumen when the rotary valve is open.

In regards to claim 17, Zadno-Azizi discloses a system for treating a vessel in a body as recited in claim 9 wherein a detachable valve actuator (220) is operably attached to the hollow guidewire (18) and the rotary shaft (32). The valve actuator (220) is part of the inflation adaptor (200). The valve actuator moves the main shaft (33), which is attached to the rotary shaft (32) to and from the open and closed positions. See column 20, lines 4-67 for a complete description. See Figures 8-9. Figures 16 and 17 show another embodiment of an inflation adaptor (800) with an actuator (820). The actuator (820) operates in a similar fashion to the previous actuator (220), but can be adapted for the second embodiment of the rotary valve as seen in Figure 12. Column 23, lines 64-67.

In regards to claim 18, Zadno-Azizi discloses a system for treating a vessel in a body as recited in claim 17 wherein an inflation fluid port (212) is operably attached to a detachable valve actuator (220). See Figures 8-9. The second embodiment also shows an inflation fluid port (812) attached to a detachable valve actuator (820). See Figures 16-17.

Zadno-Azizi discloses methods of operating a balloon catheter that includes all of the limitations of claim 19. The inherent use of either embodiment of Zadno-Azizi's invention would meet the limitations disclosed in claim 19. In the first embodiment the rotary shaft (32) is pulled longitudinally so that the plug (36) is proximal to the inflation hole (22). As the shaft (32) is pulled the biasing spring (37) applies torque to the shaft

Art Unit: 3763

(32) and can cause it to twist. The shaft (32) can therefore be seen as a rotary shaft in the broadest possible interpretation. When the plug (36) is proximal to the inflation hole (22) the rotary shaft is in an open position and fluid can be injected through the inflation hole (22) to inflate the balloon (20) at the distal of the hollow guidewire (18). In the second embodiment (Fig. 12) the rotary shaft (568) is rotated so that the channel (572) lines up with the inflation hole (522). When the channel (572) and the hole (522) are aligned, the rotary shaft (568) is in the open position and fluid can be injected into the lumen of the hollow guidewire (518) to inflate the balloon (not shown) at the distal end.

In regards to claim 20, Zadno-Azizi discloses a method of operating a balloon as recited in claim 19 wherein a valve actuator (220) is coupled to the rotary shaft (32) and the hollow guidewire (18) as described previously. The second embodiment is also operated in a similar fashion. The valve actuator (820) can be used with rotary valves of the second embodiment.

In regards to claim 21, Zadno-Azizi discloses a method of operating a balloon as recited in claim 20 wherein fluid is injected through an inflation port (212) which is coupled to the valve actuator (220). The second embodiment also uses an inflation port (812) coupled to a valve actuator (820) to inject fluid.

In regards to claim 22, Zadno-Azizi discloses a method of operating a balloon as recited in claim 21 wherein rotating the rotary shaft (32) to a closed position and detaching the valve actuator (220) would leave the balloon (20) inflated. In the second embodiment rotating the rotary shaft (568) to a closed position and detaching the valve actuator (820) would also leave the balloon inflated. See Claim 17, Column 32.

In regards to claim 23, Zadno-Azizi discloses a method of operating a balloon as recited in claim 22 wherein reattaching the valve actuator (220) to the rotary shaft (32) and hollow guidewire (18) and moving the rotary shaft (32) to an open position allows for extracting fluid from the balloon (20) to deflate it. In the second embodiment, the valve actuator (820) can be reattached to the rotary shaft (568) and the hollow guidewire (518) to open the rotary shaft (568) for the purpose of deflating the balloon. See claims 18 and 19, Column 32.

In regards to claim 24, Zadno-Azizi discloses a method of operating a balloon as recited in claim 23 wherein the rotary shaft (32) can be rotated to a closed position and the detachable valve actuator (220) can be removed after the balloon (20) is deflated. In the second embodiment, the rotary shaft (568) can be rotated to a closed position and the detachable valve actuator (820) can be removed after the balloon is deflated.

Claims 1,6,9, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Grausz (4,026,298).

Grausz also discloses a rotary valve for a balloon catheter that includes all of the limitations of claim 1. See Figures 1-4 and the respective portions of the specification. Grausz shows a rotary valve (49) with a portion of the rotary shaft (33) disposed within the hollow guidewire (32). The threaded portion (47) of rotary shaft (33) and guidewire (32) shows that the valve (49) is capable of rotation and therefore can be seen as a rotary valve.

In regards to claim 6, Grausz discloses a rotary valve for a balloon catheter as recited in claim 1 wherein a containment groove disposed on the rotary shaft (49) is

Art Unit: 3763

mated to a protrusion extending from the hollow guidewire (32) in the form of threads (47).

Grausz also discloses a system for treating a vessel in a body that includes all of the limitations of claim 9. See Figures 1-3 and the respective portions of the specification. Grausz shows a hollow guidewire (32) with a rotary valve (49) that includes a rotary shaft (33) disposed within the proximal end of the hollow guidewire (32). An inflatable balloon (22) is attached near the distal end of guidewire (32).

In regards to claim 14, Grausz discloses a system for treating a vessel in a body as recited in claim 9 wherein a containment groove disposed on the rotary shaft (49) is mated to a protrusion extending from the hollow guidewire (32) in the form of threads (47).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 3,726,282 A to Patel
U.S. Patent No. 4,026,298 A to Grausz
U.S. Patent No. 4,429,856 A to Jackson
U.S. Patent No. 4,850,350 A to Jackson
U.S. Patent No. 5,399,172 A to Martin et al.
U.S. Patent No. 5,472,432 A to Martin
U.S. Patent No. 6,050,972 A to Zadno-Azizi et al.
U.S. Patent No. 6,090,083 A to Sell et al.
U.S. Patent No. 6,368,317 B2 to Chang
U.S. Patent No. 6,475,185 B1 to Rauker et al.
U.S. Patent No. 6,743,208 B1 to Coyle

Art Unit: 3763

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TS



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